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H.B. 73
135th General Assembly

Bill Analysis

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Version: As Passed by the House

Primary Sponsors: Reps. Gross and Loychik

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SUMMARY

- Authorizes a prescriber to prescribe an off-label drug and generally requires a pharmacist to dispense, and a hospital or inpatient facility to allow the dispensing of, the drug, including when a patient has neither been tested or screened for nor exposed to a particular disease, illness, or infection.
- Authorizes, under certain circumstances, an off-label drug to be brought into a hospital or inpatient facility for administration to a patient.
- Establishes a process by which an outpatient physician prescriber may obtain temporary hospital or inpatient facility privileges to participate in a hospital or facility patient's care in the narrowed scope of practice regarding the administering and monitoring of a prescribed off-label drug.
- Grants qualified immunity from liability for harm resulting from the dispensing or use of an off-label drug in accordance with the bill's provisions.
- Generally prohibits a licensing board from pursuing an administrative or disciplinary action against a prescriber who prescribes the off-label drug, a pharmacist who dispenses it, or a hospital or inpatient facility that allows it to be dispensed.
- Prohibits an administrative or disciplinary action against a licensed health care professional or a hospital or inpatient facility for expressing a medical opinion that does not align with those of the licensing board, a local board of health, or the Ohio Department of Health.
- Generally prohibits the denial of nutrition or fluids to a patient.
- Prohibits a political subdivision, public official, or state agency from enforcing any rule or order issued by a federal agency that prohibits issuing a prescription for or dispensing an off-label drug.
- Names the act the Dave and Angie Patient and Health Provider Protection Act.

DETAILED ANALYSIS

Off-label drugs – prescribing and dispensing generally

The bill authorizes a prescriber to issue for a patient a prescription for any drug, including an off-label drug – if the prescriber has obtained the patient's informed consent or the consent of the person holding the patient's health care power of attorney.[1]

The bill also requires a pharmacist to dispense the off-label drug, and a hospital or inpatient facility to allow its dispensing, except in the following circumstances:

- The pharmacist, hospital, or inpatient facility has a moral, ethical, or religious belief or conviction that conflicts with the drug's dispensing;
- The pharmacist has documented that the patient has a history of a life-threatening allergic reaction to the drug or there is a life-threatening contraindication.[2]

Definitions

- A "prescriber" includes a physician, advanced practice registered nurse, physician assistant, optometrist, or dentist.[3]
- An "off-label drug" means a drug that is both of the following: (1) approved by the federal Food and Drug Administration to treat or prevent a disease, illness, or infection, but prescribed for or used to treat or prevent another disease, illness, or infection and (2) legal for use in Ohio.[4]
- A "hospital" includes one owned or operated by the U.S. Department of Veterans Affairs, while an "inpatient facility" means a freestanding inpatient rehabilitation facility licensed by the Ohio Department of Health (ODH) or a skilled nursing facility.[5]

Authority to prescribe off-label

In general, once the federal Food and Drug Administration (FDA) approves a drug for a specific indication, it may be prescribed by a health care provider for any indication, absent state law to the contrary, if the provider judges it medically appropriate. This is often referred to as "off-label" use.[6] The bill codifies that authority.

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[1] R.C. 3792.06(B).

[2] R.C. 3792.06(C) and R.C. 4743.10, not in the bill.

[3] R.C. 4729.01, not in the bill.

[4] R.C. 3792.06(A).

[5] R.C. 3792.06(A).

[6] U.S. Food and Drug Administration, Understanding Unapproved Use of Approved Drugs "Off Label" (February 5, 2018), which is also available by conducting a keyword "off label" search on the FDA's website: fda.gov.

Test results and positive screenings

The bill specifies that the prescriber or pharmacist is not required to obtain a test result before issuing the off-label drug's prescription or dispensing the drug for the patient's use at home or for other outpatient treatment.[7] Moreover, the patient is not required by the bill to have had a positive screen for a particular disease, illness, or infection before the prescriber issues the prescription or the pharmacist dispenses the off-label drug.[8]

Exposures

The bill also specifies that the patient is not required to have been exposed to a disease, illness, or infection before a prescriber may issue a prescription for the patient's prophylactic use of the off-label drug or a pharmacist dispenses the drug for such use.[9]

Pharmacist discussion

The bill specifies that its provisions do not prevent a pharmacist from discussing a prescription with the prescriber who issued it.[10]

Hospitals and inpatient facilities

The bill contains several provisions specific to dispensing and administering an off-label drug in a hospital or inpatient facility, including when the drug is not in stock or the hospital, facility, pharmacist, or treating prescriber has a conflicting moral, ethical, or religious belief or conviction.[11]

Good faith effort to locate off-label drug

Under the bill, where an in-house treating prescriber issues for a hospital or inpatient facility patient a prescription for an off-label drug and the drug is neither in stock nor listed on the hospital's or facility's formulary, the hospital or facility pharmacist must document in the patient's medical record that a good faith effort was made to find out if the drug is available from another hospital, facility, or distributor.[12]

Access to and administration of off-label drugs

If (1) the hospital or inpatient facility pharmacist is unable to obtain an off-label drug prescribed by an in-house treating prescriber from another hospital, facility, or distributor or (2) the hospital or facility or its pharmacist declines to fill the prescription for a moral, ethical, or religious belief or conviction, and (3) the patient has access to the drug through a pharmacy

[7] R.C. 3792.06(B) and (C).

[8] R.C. 3792.06(B) and (C).

[9] R.C. 3792.06(B) and (C).

[10] R.C. 3792.06(C).

[11] R.C. 3792.06(C).

[12] R.C. 3792.06(C).

outside the hospital or facility or has the drug available at home, the bill provides for both of the following:

- The hospital or facility must permit the drug to be brought in to be "identified," or determined by the hospital or facility pharmacist as in its original packaging or labeled from an outside retail pharmacy, approved by the prescriber for use, and not outside its beyond use date,[13] for the patient's use and administration within the hospital or facility;
- When the hospital or inpatient facility or the patient's in-house treating prescriber or other in-house treating clinician is unwilling to administer the drug to the patient for a moral, ethical, or religious belief or conviction, another prescriber or prescriber's delegate may administer the drug.[14]

Temporary privileges

When a patient cannot be safely transported out of a hospital or inpatient facility and the patient or person holding the patient's health care power of attorney wishes to try an off-label drug to treat the patient's condition, but there is no in-house prescriber willing to prescribe the drug, all of the following apply under the bill:

- The patient's outpatient physician prescriber, after a prompt consultation with the patient's hospital or inpatient facility care team and a review of all of the patient's drugs, must be allowed to immediately begin applying for temporary privileges with oversight, based on criteria within the hospital or inpatient facility medical staff bylaws;
- The temporary approval process must not exceed five days;
- If the outpatient physician prescriber does not meet the medical staff bylaw requirements, the denial must be reported to ODH;
- If the outpatient physician prescriber meets the bylaw requirements, the outpatient physician prescriber must immediately be allowed to participate in the patient's care in the narrowed scope of practice regarding the administering and monitoring of the prescribed off-label drug within the hospital or facility until the patient is in a condition where the patient can be safely transported to a hospital or inpatient facility where the outpatient physician prescriber is credentialed.[15]

  In such a case, both of the following provisions apply:

- The hospital or facility must permit the drug to be brought in to be identified, as described above in "**Access to and administration of off-label drugs**";

[13] R.C. 3792.06(A).

[14] R.C. 3792.06(C).

[15] R.C. 3792.06(C).

- When the hospital or inpatient facility or the patient's in-house treating prescriber or other in-house treating clinician is unwilling to administer the drug to the patient for a moral, ethical, or religious belief or conviction, another prescriber or prescriber's delegate may administer the drug.[16]

Out-of-pocket costs

The bill requires an off-label drug available from another hospital, inpatient facility, or distributor to be offered to a patient at an upfront out-of-pocket cost to the patient and also authorizes the hospital or facility to require payment prior to ordering the drug.[17]

The bill also specifies that, before an off-label drug is ordered, a patient may be required to pay out-of-pocket for a drug that is prescribed by an outpatient physician prescriber who has obtained temporary privileges at a hospital or inpatient facility.[18]

Immunity

The bill grants immunity from administrative or civil liability for any harm that may arise from the dispensing or use of an off-label drug to a pharmacist who must dispense the drug, or to a hospital or inpatient facility that must allow the drug's dispensing, but has an objective, good faith, and scientific objection to the administration or dosage of the drug for the patient if both of the following conditions are met:

- At the time of dispensing, the pharmacist, hospital, or inpatient facility documents in the patient's medical record the objective, good faith, and scientific objection, by stating with particularity the basis of the objections, which must be based on an individualized assessment of the patient and the off-label drug;
- The pharmacist submits to the Board of Pharmacy or the hospital or inpatient facility submits to ODH the objective, good faith, and scientific objection, again by stating with particularity the basis of the objection, which must be based on an individualized assessment of the patient and the off-label drug.[19]

The bill also grants an in-house pharmacist, hospital, or inpatient facility and the in-house physician responsible for the patient's care immunity from administrative and civil liability for any harm that may arise from the patient's use of the off-label drug prescribed by an outpatient physician prescriber starting from the date of dispensing.[20] The bill neither defines nor describes administrative liability.

[16] R.C. 3792.06(C).

[17] R.C. 3792.06(C).

[18] R.C. 3792.06(C).

[19] R.C. 3792.06(C).

[20] R.C. 3792.06(C).

Disciplinary actions

The bill prohibits the following from considering any action taken by a prescriber, pharmacist, hospital, or inpatient facility under the bill to be unlawful, unethical, unauthorized, or unprofessional conduct: the State Medical Board, Ohio Board of Nursing, State Dental Board, State Vision Professionals Board, State Board of Pharmacy, and ODH.[21] It further prohibits such an entity from pursuing an administrative or disciplinary action against the prescriber, pharmacist, hospital, or inpatient facility, except in cases of recklessness or gross negligence.[22]

Medical opinions

The bill prohibits a board that licenses or regulates a health care professional or ODH from pursuing an administrative or disciplinary action against a prescriber, pharmacist, or other licensed health professional or a hospital or inpatient facility for publicly or privately expressing a medical opinion that does not align with the opinions of the board, a local board of health, or ODH.[23]

Denial of fluids or nutrition

The bill prohibits a hospital or inpatient facility patient from being denied sufficient means of fluids or nutrition, unless (1) that wish is clearly stated in the patient's end of life health directive, as that directive is defined by the patient or patient's health care power of attorney or (2) the denial is necessary for a medical procedure, including a diagnostic or surgical procedure. The denial must be for the shortest amount of time medically possible and with the informed consent of the patient or person holding the patient's health care power of attorney.[24]

Enforcement of federal rules or orders

The bill prohibits a political subdivision, public official, or state agency from enforcing any rule or order issued by a federal agency that prohibits issuing a prescription for or dispensing an off-label drug.[25]

[21] R.C. 3792.06(D).

[22] R.C. 3792.06(D).

[23] R.C. 3792.06(D).

[24] R.C. 3792.06(F).

[25] R.C. 3792.06(E).

HISTORY

Action	Date
Introduced	02-27-23
Reported, H. Health Provider Services	06-21-23
Passed House (75-17)	06-21-23

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